K131748

510(K) Summary

Submitter
Osseofuse, Inc.
Kelvin Yoo
5023 North Parkway Calabasas,
Calabasas, CA 91302
Email: kelvin0706@hotmail.com
Tel. 888) 446 – 9995
Fax. 310) 356 – 3183

Official Correspondent
Kodent Inc.
April Lee
325 N. Puente st. Unit B
Brea, CA 92821
Email: kodentinc@gmail.com
Phone: 714-525-0114
Fax: 714-525-01116

Device Information

- Trade Name: OsseoFuse Dental Implant System
- Common Name: Endosseous dental implant
- Classification Name: Implant, Endosseous, Root-Form
- Product Code: DZE
- Regulation Number: 872.3640
- Device Class: Class II
- Date prepared: 10/29/2013

OCT 3 1 2013

General Description

The OsseoFuse Dental Implant System includes Hexa-Plus S fixture, Hexa-Plus S abutment, and Hexa-Plus S Lab Components. This system made of Titanium intended to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. It is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The surface of this system has been treated with R.B.M (Resorbable Blast Media).

Hexa-plus S Fixture is only part to be implanted into bone, and to provide connection of prosthetic devices or other components of a dental implant set with human body (mandibular or maxillary bone). Surface of part to be implanted into bone is treated by RBM method .

The purpose of this submission is

- to add new fixtures,
  Dia 5.25mm X L 8.5/10/11.5/13mm
  Dia 6.5mm X L 8.5/10/11.5/13mm
  Dia 7.5mm X L 8.5/10/11.5/13mm
- to add new abutments, Implant cover screw, wide cover screw, one-step abutment, CCM casting abutment, and plastic temporary abutment.

Indication for Use

The OsseoFuse Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. This system is intended for delayed loading.

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

- Osseofuse Dental Implant System by Osseofuse, Inc. (K110577)

	Subject Device	Predicate Device
510(K) Number	N/A	K110577
Device Name	OsseoFuse Dental Implant System	OsseoFuse Dental Implant System
Manufacturer	KJ Meditech Co., Ltd.	KJ Meditech Co., Ltd.
Indications for Use	Identical to the predicate	Intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement-retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.
Design	Identical to the predicate • Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck with micro-thread provides crestal seal. • 1mm smooth titanium surface allows soft tissue maintenance. • Body Design: Subject device has one additional cutting edge than predicate device and slightly more aggressive thread design. This change increases	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck with micro-thread provides crestal seal. • 1mm smooth titanium surface allows soft tissue maintenance. • Body Design: Tapered design enables placement near impringing anatomical structures while maximizing prosthetic table diameter for natural emergence profile.

	self-drilling ability of the fixture. Rest of the features are identical to the predicate.	
Appearance		
Endosseous Implant Material	Identical to the predicate	Ti 6Al 4V ELI, Gr.23
Surface Treatment	Identical to the predicate	RBM Treatment on the fixture body
Implant Sterile	Identical to the predicate	Yes
Sterilization Method	Identical to the predicate	Gamma
Implant Diameters	5.25mm, 6.5mm, 7.5mm	3.75mm, 4.1mm, 4.5mm, 5.25mm
Implant Lengths	8.5, 10, 11.5, 13 mm	8.5 – 16.0 mm
Product Code	DZE	DZE

Comparison to Predicate Devices:

The OsseoFuse Dental Implant System has a substantially equivalent intended use as the identified predicate. The OsseoFuse Dental Implant System is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutments, and they are all constructed of titanium.

The subject and predicate device are similar in indications, technology, connection type, surface treatment and functions. The differences between the subject device and the predicate device are the design and the diameters of the fixture.

When compared with predicate device, no new questions of safety or effectiveness have been raised.

There is no difference between the subject and predicate with respect to the indications or technology.

Non-Clinical Test Data:

Based n a risk analysis of the modifications, no additional testing was added for this submission.

Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification concludes that the OsseoFuse Dental Implant System is substantially equivalent to predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 31, 2013

OsseoFuse, Incorporated
C/O Ms. April Lee
Consultant
Kodent, Incorporated
325 North Puente Street Unit B
BREA CA 92821

Re: K131748
Trade/Device Name: OsseoFuse Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: September 30, 2013
Received: October 2, 2013

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K131748

Device Name: OsseoFuse Dental Implant System

Indication for Use:

The OsseoFuse Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures. This system is intended for delayed loading.

Prescription Use ____X_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page 1 of 1

Andrew I. Steen -S
2013.10.31 10:15:07 -04'00'